



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2014-0326; FRL-9924-24]**

**Sodium L-lactate and Sodium DL-lactate; Exemption from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of sodium L-lactate and sodium DL-lactate when used as inert ingredients (surfactants) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. Exponent, on behalf of Archer Daniels Midland Company, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sodium L-lactate and sodium DL-lactate.

**DATES:** This regulation is effective *[insert date of publication in the Federal Register]*.

Objections and requests for hearings must be received on or before *[insert date 60 days after date of publication in the Federal Register]*, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0326, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency

Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfRNotices@epa.gov](mailto:RDfRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0326 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0326, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Petition for Exemption**

In the **Federal Register** of August 1, 2014 (79 FR 44729) (FRL-9911-67), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10693) by Exponent, 1150 Connecticut Ave., NW Washington, DC 20036, on behalf of Archer Daniels Midland Company, 4666 E. Faries Parkway, Decatur, IL 62526. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of sodium L-lactate (CAS Reg. No. 867-56-1) and sodium DL-lactate (CAS Reg. No. 72-17-3) when used as an inert ingredients (surfactants) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. That document referenced a summary of the petition prepared by Exponent, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

## **III. Inert Ingredient Definition**

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may

not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for sodium L-lactate and sodium DL-lactate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with sodium L-lactate and sodium DL-lactate follows.

*A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by sodium L-lactate and sodium DL-lactate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The Agency has reviewed the data submitted by the petitioner. The data submitted includes data on lactic acid. Sodium lactate, the sodium salt of lactic acid, is expected to readily disassociate into the lactate and sodium ions in the body upon ingestion. Lactic acid also typically converts to lactate in the body. Because sodium L-lactate and sodium DL-lactate readily disassociate into the lactate and sodium ions in the body, the Agency has concluded that the data on L-lactic acid (often referred to as lactic acid) can be used in conjunction with the data on another lactate salt, calcium lactate, and that these data are adequate to characterize the toxicity of sodium L-lactate and sodium DL-lactate.

Acute oral and inhalation toxicity of lactic acid to rats and acute dermal toxicity of lactic acid to rabbits are low (oral LD<sub>50</sub> > 3,500 milligrams/kilogram (mg/kg); inhalation LC<sub>50</sub> >5

milligrams/Liter (mg/l); dermal LD<sub>50</sub> > 2,000 mg/kg). L-lactic acid is severely irritating and corrosive to rabbit skin. Dilute solutions of lactic acid are irritating to the eyes of rabbits. L-Lactic acid is not a dermal sensitizer in guinea pigs. In an oral feeding study, two groups of (strain not-specified) received daily doses of 1,000 and 2,000 mg/kg/day of sodium lactate (as lactic acid) over 14 to 16 days. Body analyses of the animals showed no accumulation of lactate. No developmental or reproductive toxicity studies are available for sodium L-lactate or sodium DL-lactate; however, a developmental toxicity study for lactic acid resulted in no maternal or developmental effects and none of the reproductive parameters were affected in mice at 570 mg/kg/day. Additionally, sodium L-lactate and DL-lactate are not expected to be mutagenic or carcinogenic based on the presence of the lactic acid metabolite in the human body. Lactic acid is transported to the liver and converted by lactic acid dehydrogenase to pyruvate. Pyruvate, in turn can be converted into free glucose, stored as glycogen, and utilized in other metabolic transformations (Krebs cycle). In addition, in a 2-year combined chronic toxicity/carcinogenicity study in rats with calcium lactate, there was no evidence of carcinogenicity or systemic toxicity at doses up to 5,000 mg/kg/day.

#### *B. Toxicological Points of Departure/Levels of Concern*

Sodium L-lactate and sodium DL-lactate are naturally occurring compounds and when disassociated, are normal constituents of the human body. No toxicological endpoint of concern has been identified.

#### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to sodium L-lactate and sodium DL-lactate, EPA considered likely exposure from the use of sodium L-lactate and sodium DL-lactate as an inert ingredient in pesticides applied to growing crops or to raw agricultural commodities after harvest. Since no toxicological endpoint of concern has been

identified and since the metabolic processes involving sodium L-lactate and sodium DL-lactate are well understood, the Agency has determined that a quantitative dietary exposure assessment is not necessary. While dietary exposure may result from the use of sodium L-lactate and sodium DL-lactate as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest, the amount of sodium L-lactate and sodium DL-lactate contained in pesticide formulations and applied to growing crops or to raw agricultural commodities after harvest would be at levels far below its natural occurrence in foods and endogenous production in the human body.

By comparison, L-lactic acid (CAS Reg. No. 79-33-4) is a naturally occurring compound found in many foods and is also a human metabolite that results from various biochemical pathways. Humans are generally exposed to lactic acid on a daily basis in significant quantities because it is naturally present in many food products that are derived through natural fermentation, such as cheese, yogurt, soy sauce, sourdough, meat products, and pickled vegetables.

2. *Dietary exposure from drinking water.* Dietary exposure from drinking water to sodium L-lactate and sodium DL-lactate can occur by drinking water that has been contaminated by run-off from a pesticide treated area. Since an endpoint for risk assessment was not identified, a quantitative dietary exposure assessment from drinking water for sodium L-lactate and sodium DL-lactate was not conducted.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

There is a potential for residential exposure to pesticide products containing sodium L-lactate and sodium DL-lactate, however, quantitative residential exposure



assessment was not conducted since no endpoint of concern was identified.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found sodium L-lactate and sodium DL-lactate to share a common mechanism of toxicity with any other substances, and sodium L-lactate and sodium DL-lactate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that sodium L-lactate and sodium DL-lactate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children.

Because of the non-toxic nature of sodium L-Lactate and sodium DL-lactate, there are no threshold effects that would trigger the application of section 408(b)(2)(C).

#### *E. Aggregate Risks and Determination of Safety*

Taking into consideration all available information on sodium L-lactate and sodium DL-lactate, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to sodium L-lactate and sodium DL-lactate under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.910 for residues of sodium L-lactate and sodium DL-lactate when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest, is safe under FFDCA section 408.

#### **V. Analytical Enforcement Methodology**

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

#### **VI. Conclusion**

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for sodium L-lactate (CAS Reg. No. 867-56-1) and sodium DL-lactate (CAS Reg. No. 72-17-3) when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.

#### **VII. Statutory and Executive Order Reviews**

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045,

entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

#### **VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 12, 2015.

Susan Lewis,  
*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Amend §180.910, by adding alphabetically the following inert ingredients to the table to read as follows:

**§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * *	* * *	*
Sodium DL-lactate (CAS Reg. No. 72-17-3)		Surfactant
* * *	* * *	*
Sodium L-lactate (CAS Reg. No. 867-56-1)		Surfactant
* * *	* * *	*